ACIP Votes to Recommend Routine Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines (Tdap) for Adolescents

Two Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) products were licensed by the FDA in 2005 as single dose booster vaccines to provide protection against tetanus, diphtheria, and pertussis. GlaxoSmithKline's BOOSTRIX[®] is indicated for persons 10–18 years of age (www.fda.gov/cber/label/tdapgla050305LB.pdf), and sanofi pasteur's ADACEL™ is indicated for persons 11–64 years of age (www.fda.gov/cber/label/tdapave061005LB.pdf). On June 30, 2005 the Advisory Committee on Immunization Practices (ACIP) voted to recommend the routine use of Tdap vaccines in adolescents 11–18 years of age in place of tetanus and diphtheria toxoids (Td) vaccines (www.cdc.gov/nip/pr/pr tdap jun2005.htm).

Pertussis is a highly contagious respiratory tract infection; immunity from childhood vaccination wanes over time leaving adolescents susceptible. In 2004, U.S. adolescents 11–18 years of age made up 34% (8,897) of the total 25,827 reported cases; reported cases underestimate the true burden of pertussis in adolescents. The clinical presentation of pertussis in adolescents ranges from mild cough illness to classic pertussis (i.e., paroxysms of cough, post-tussive emesis, and inspiratory whoop). The morbidity of pertussis in adolescents can be substantial with prolonged cough illness lasting weeks to months. Hospitalization and complications (e.g., pneumonia and rib fractures) occur up to 2% of reported cases. Pertussis outbreaks in schools with adolescents are disruptive and lead to significant public health control efforts.

The primary objective of the adolescent pertussis booster vaccination program is to protect adolescents against pertussis. Key ACIP recommendations for Tdap (single dose) and Td use in adolescents 11–18 years of age are summarized below. These ACIP recommendations are under review by the Director of CDC and the Department of HHS and will become official when published in CDC's Morbidity and Mortality Weekly Report (MMWR) (www.cdc.gov/mmwr/).

Routine Tdap Vaccination among Adolescents 11-18 Years of Age

- Adolescents 11–18 years of age should receive a single dose of Tdap instead of Td for booster immunization against tetanus, diphtheria and pertussis if they have completed the recommended childhood DTP/DTaP vaccination series* and have not received Td or Tdap. The preferred age for Tdap vaccination is 11–12 years; routinely administering Tdap to young adolescents will reduce the morbidity associated with pertussis in adolescents.
- Adolescents 11–18 years of age who received Td, but not Tdap, are encouraged to receive a single dose of Tdap to provide protection against pertussis if they have completed the recommended childhood DTP/DTaP vaccination series.* A interval of at least 5 years between Td and Tdap is encouraged to reduce the risk of local or systemic reactions after Tdap vaccination. However, intervals shorter than 5 years between Td and Tdap may be used. The benefit of using Tdap at shorter intervals to protect against pertussis generally outweigh the risk of local or systemic reactions after vaccination in settings with increased risk of pertussis or its complications (see <u>Pertussis Outbreaks and Other Setting with Increased Risk of Pertussis or its Complications</u>).
- Vaccine providers should administer Tdap (or Td) and tetravalent meningococcal conjugate vaccine ([MCV4] Menactra,™) (which contains diphtheria toxoid) during the same visit if both vaccines are indicated and available (MCV4 recommendations available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm and www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1006a1.htm).[†]
- Tdap (or Td) should be administered with other vaccines that are indicated during the same visit when feasible. Each vaccine should be administered using a separate syringe at different anatomic sites.
 Some experts recommend administering no more than two injections per deltoid, separated by one inch during one visit.

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Special Situations for Tdap (single dose) and Td Use among Adolescents 11-18 Years of Age

- <u>Nonsimultaneous vaccination:</u> If simultaneous vaccination is not feasible, inactivated vaccines may be administered at any time before or after a different inactivated or live vaccine. Tdap (or Td) and MCV4 vaccines (which contain diphtheria toxoid) may be administered using any sequence. It is possible that persons who recently received one diphtheria toxoid-containing vaccine might have increased rates of adverse reactions after a subsequent diphtheria toxoid-containing vaccine when diphtheria toxoid antibody titers remain elevated from the previous vaccination.[†]
- Pertussis Outbreaks and Other Setting with Increased Risk of Pertussis or its Complications: Vaccine providers may administer Tdap after Td to adolescents 11–18 years of age at intervals shorter than 5 years, particularly when the benefit of providing protection against pertussis is likely to be increased (e.g., pertussis outbreaks, close contact with an infant <12 months of age). The safety of intervals as short as approximately 2 years between Td and Tdap is supported by a Canadian study among children and adolescents.[‡] Post-exposure chemoprophylaxis and other pertussis control guidelines are available at www.cdc.gov/nip/publications/pertussis/guide.htm and www.cdc.gov/mmwr/preview/mmwrhtml/rr5414a1.htm.
- <u>Lack of Availability of Tdap or MCV4:</u> If Tdap and MCV4 are both indicated for adolescents but only one vaccine is available, the available vaccine should generally be administered.
- <u>Use of Td when Tdap is Not Available</u>: When Tdap is indicated but not available, vaccine providers should administer Td if the last DTP/DTaP/DT/Td vaccine was ≥10 years earlier to provide protection against tetanus and diphtheria. Td can be deferred temporarily when the last DTP/DTaP/DT/Td was administered <10 years earlier and the adolescent is likely to return for follow-up. Vaccine providers should maintain a system to recall adolescents when Tdap/Td vaccination is deferred.
- <u>Tetanus Prophylaxis in Wound Management:</u> Adolescents who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td if they have not previously received Tdap; if Tdap is not available or was previously administered, adolescents who need a tetanus toxoid-containing vaccine should receive Td.
- <u>History of Pertussis:</u> Adolescents who have a history of pertussis generally should receive Tdap according to the routine recommendations.
- No History of Vaccination with Pertussis Components: Adolescents who have not received pertussis vaccines but completed the recommended tetanus-diphtheria vaccination series* with pediatric DT or Td generally should receive Tdap according to the routine recommendations if they do not have a contraindication to the pertussis components.
- No History of DTP/DTaP/Td/Tdap Vaccination: Adolescents who have never received tetanus-diphtheria-pertussis vaccination should receive a series of three vaccinations. The preferred schedule is a single Tdap dose, followed by a dose of Td ≥4 weeks after the Tdap dose and a second dose of Td 6 to 12 months after the Td dose. Tdap may substitute for any one of the 3 Td doses in the series.
- <u>Vaccination during Pregnancy:</u> Pregnancy is not considered a contraindication to Tdap or Td vaccination. Guidance on the use of Tdap during pregnancy is under consideration by ACIP. At this time: 1. adolescents who received the last tetanus toxoid-containing vaccine <10 years should generally receive Tdap in the post-partum period, according to the routine vaccination recommendations and interval guidance and 2. adolescents who received the last tetanus toxoid-containing vaccine ≥10 years previously should generally receive Td in preference to Tdap (during the second or third trimester).

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Contraindications, Precautions and Reasons to Defer Tdap or Td:

- <u>Contraindications:</u> History of 1. serious allergic reaction (i.e., anaphylaxis) to vaccine components or 2. encephalopathy (e.g., coma, prolonged seizures) not attributable to an identifiable cause within 7 days of administration of a vaccine with pertussis components.
- <u>Precautions and Reasons to Defer Vaccination:</u> 1.Guillain-Barré Syndrome (GBS) ≤6 weeks after a previous dose of a tetanus toxoid-containing vaccine; 2. progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy until the condition has stabilized;[‡] 3. Acute illness; and 4. history of an Arthus reaction after a tetanus toxoid-containing and/or diphtheria toxoid-containing vaccine administered <10 years previously.

<u>Reporting of Adverse Events after Vaccination:</u> All clinically significant adverse events should be reported to VAERS, even if causal relationship to vaccination is uncertain. VAERS reporting forms and information are available electronically at www.vaers.org/ or by calling (800) 822-7967. Providers are encouraged to report electronically at https://secure.vaers.org/VaersDataEntryintro.htm.

<u>Other Considerations</u>: On October 26, 2005, the ACIP voted to recommend a single dose of Tdap for adults 19–64 years of age (http://www.cdc.gov/nip/recs/provisional_recs/default.htm). Recommendations for use of Tdap among health-care providers, pregnant women, and adults https://www.cdc.gov/nip/recs/provisional_recs/default.htm). Recommendations for use of Tdap among health-care providers, pregnant women, and adults https://www.cdc.gov/nip/recs/provisional_recs/default.htm).

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^{*} Five doses of DTP/DTaP before the seventh birthday; if the fourth dose was administered on or after the fourth birthday, the fifth dose is not needed. Children who began the tetanus-diphtheria vaccination series at ≥7 years of age required three doses of Td to complete the primary series.

A pre-licensure study demonstrated that simultaneous vaccination with Td and MCV4 was acceptably safe; the safety of simultaneous vaccination with Tdap and MCV4 has been inferred from this study. Td followed one month later by MCV4 was studied and rates of local reactions were comparable to simultaneous vaccination. Other schedules of MCV4 and Td, and MCV4 and Tdap have not been studied (http://www.fda.gov/cber/label/mpdtave011405LB.pdf).

[‡] This condition is a precaution for the pertussis components; it is a precaution Tdap use among adolescents but a contraindication for use of pediatric DTaP among infants and children (CDC ACIP, MMWR 2002).